Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

Effect of concentrated beetroot juice consumption on anthropometric measures, glycemic control, lipid profile, blood pressure, plasma systematic and vascular inflammation and oxidative stress, and NF-kB in peripheral blood mononuclear cells in patients with type 2 diabetes: Randomized clinical trial study

Protocol summary

Study aim

Investigation of the effects of concentrated beetroot juice supplementation on glycemic control, lipid profile, hypertension, systemic inflammatory markers and oxidative stress and NF-κB in peripheral blood mononuclear cells and anthropometric measures in patients with type 2 diabetes.

Design

A randomized, controlled, open-label , phase 3 trial on 70 patient. Patients will be matched for gender and age then will be allocated to the concentrated group (A) and control group (B). Randomization will be done by blocked randomization (using 18-block charts and 70 sealed envelopes named A and B).

Settings and conduct

Patients with diabete 2 referring to the Shahid Ghasemi Clinic, Sari, Iran, who have criteria for entering the study, will write informed consent. At baseline ,they will be randomly assigned into intervention group who will receive 25 ml of concentrate, daily for 12 weeks and the control group who will receive routine care. At the beginning and after the intervention, meanwhile evaluating the anthropometric measures, 10 cc blood will be taken from patients after 12-14 hours fasting .

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with noninsulin dependent diabetes for 1 to 10 years, aged between 35 -70 years and BMI between 20–25 kg/ m2. Exclusion criteria: Having inflammatory, hepatic and renal disease, receiving multivitamin supplements or herbal medicines during last 3 months or taking nitrate-containing drugs.

Intervention groups

Patients will randomly be allocated to the consternate (n = 35) and control group (n = 35) respectively for consumption in either order, a 12-week period of supplementation with 25 ml concentrated beetroot juice daily or without any intervention.

Main outcome variables

Fasting plasma glucose, HbA1C,Homeostatic model assessment of insulin resistance& pancreatic β-cell function (HOMA-IR and HOMA-β respectively).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150815023617N5**
Registration date: **2020-12-06, 1399/09/16**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-06, 1399/09/16**
Update count: **0**

Registration date

2020-12-06, 1399/09/16

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 22077424

Email address

golbonsohrab@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2020-10-10, 1399/07/19
Expected recruitment end date
2021-02-07, 1399/11/19
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of concentrated beetroot juice consumption on anthropometric measures, glycemic control, lipid profile, blood pressure, plasma systematic and vascular inflammation and oxidative stress, and NF-kB in peripheral blood mononuclear cells in patients with type 2 diabetes: Randomized clinical trial study

Public title
Investigation of the effect of concentrated beetroot juice consumption in patients with type 2 diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Tendency to cooperate Patients with type 2 diabetes for 1-10 years Age between 35 to70 years old BMI between 20-25 kg/m2 No pregnancy or breast-feeding Patients who are only being treated with oral hypoglycemic agents No alcohol and substance abuse history
Exclusion criteria:
Patients who are using insulin Having chronic kidney, liver, or inflammatory diseases Taking multivitamin and herbal supplements in the past 3 months Taking glucocorticoids and nonsteroidal anti-inflammatory drugs Taking of nitrate-containing drugs such as nitroglycerin, isosorbide, nitropress, etc. History of microvascular and macrovascular diseases (such as history of angioplasty, foot vascular surgery) Patients with uncontrolled diabetes (HbA1C more than or equal 8.5%)
Age
From **35 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
This study is a simply randomized, controlled, open-labeled trial. Patients will match for gender and age then will be allocated to the beetroot group-group A- (n = 35) and control group- group B- (n = 35) by blocked randomization (using the table of four blocks (A and B). A computer algorithm written in SAS® (Cary, NC) will be used for performing block randomization with randomly selected block sizes of 4. Finally, 18-block will be randomly selected and these blocks will be placed behind each other and 70 sealed envelopes named A and B will be provided. Participants will randomly choose one of these envelopes at the beginning of the study. These envelopes will be referred to individuals respectively for consumption in either order, an a12-week period of daily supplementation with 25 ml concentrated beetroot juice or without any intervention.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of medical sciences
Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town
City
Tehran
Province
Tehran
Postal code
1981618573
Approval date
2020-07-25, 1399/05/04
Ethics committee reference number
IR.SBMU.nnftri.Rec.1399.035

Health conditions studied

1

Description of health condition studied
Diabetes
ICD-10 code
E08
ICD-10 code description
Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
Plasma level of fasting plasma glucose
Timepoint
At the beginning (before the start of the study) and at

the end of the study (12 weeks after the start of beet juice consumption)

Method of measurement

Measuring by the colorimetric method based on the enzymatic reactions of invertase and glucose oxidase-peroxidase (GOD-POD).

2

Description

HbA1C

Timepoint

At the beginning (before the start of the study) and at the end of the study (12 weeks after the start of beet juice consumption)

Method of measurement

Chromatography

3

Description

HOMA-β: The homeostasis model assessment of pancreatic β-cell function

Timepoint

At the beginning (before the start of the study) and at the end of the study

Method of measurement

Calculating by formula: HOMA-B=20× Insulin (μU/m/glucose(mg/dl) −3.5

4

Description

HOMA-IR: Homeostatic model assessment of insulin resistance

Timepoint

At the beginning (before the start of the study) and at the end of the study

Method of measurement

Calculating by formula: HOMA-IR=(glucose(mg/dl)× Insulin(μU/ml))/22.5

Secondary outcomes

1

Description

Anthropometric measures: Weight

Timepoint

At the beginning of the study (before the intervention) and at the end of the study (12 weeks after consuming beet juice)

Method of measurement

Using a digital scale

2

Description

Systolic and diastolic blood pressure

Timepoint

At the beginning of the study (before the intervention) and at the end of the study (12 weeks after consuming beet

Method of measurement

Standardized mercury sphygmomanometer

3

Description

HDL

Timepoint

At the beginning of the study (before the intervention) and at the end of the study (12 weeks after consuming beet)

Method of measurement

Photometric enzymatic method

4

Description

Total -cholesterol

Timepoint

At the beginning of the study (before the intervention) and at the end of the study (12 weeks after consuming beet)

Method of measurement

Photometric enzymatic method

5

Description

LDL-cholesterol

Timepoint

At the beginning of the study (before the intervention) and at the end of the study (12 weeks after consuming beet)

Method of measurement

Using the Friedwald formula: LDL=TC −HDL − (TAG/5)

6

Description

Intercellular Adhesion Molecule 1(ICAM-1)

Timepoint

At the beginning of the study (before the intervention) and at the end of the study (12 weeks after consuming beet)

Method of measurement

ELISA

7

Description

Interleukin 6

Timepoint

At the beginning of the study (before the intervention) and at the end of the study (12 weeks after consuming beet)

Method of measurement

ELISA

8

Description

high-sensitivity C-reactive protein (hs-CRP)

Timepoint

At the beginning of the study (before the intervention) and at the end of the study (12 weeks after consuming beet)

Method of measurement

ELISA

9

Description

Malondialdehyde (MDA)

Timepoint

At the beginning of the study (before the intervention) and at the end of the study (12 weeks after consuming beet)

Method of measurement

Photometric enzymatic method

10

Description

Plasma nitrate and nitrite

Timepoint

At the beginning of the study (before the intervention) and at the end of the study (12 weeks after consuming beet)

Method of measurement

Griess Colorimetric method

11

Description

Tumor necrosis factor(TNF-α)

Timepoint

At the beginning of the study (before the intervention) and at the end of the study (12 weeks after consuming beet)

Method of measurement

ELISA

12

Description

Nuclear factor-κB (NF-κB)

Timepoint

ELISA

Method of measurement

At the beginning of the study (before the intervention) and at the end of the study (12 weeks after consuming beet)

13

Description

Height

Timepoint

At the beginning of the study (before the intervention) and at the end of the study (12 weeks after consuming beet)

Method of measurement

Using a Seca portable height gauge

14

Description

Body mass index

Timepoint

At the beginning of the study (before the intervention) and at the end of the study (12 weeks after consuming beet)

Method of measurement

Weight in kilogram / the square of the height in centimeters

Intervention groups

1

Description

Intervention group: A12-week period of daily supplementation with 25 ml concentrated beetroot juice . Concentrated beetroot juice will be prepared by Takdaneh, Inc., Iran, without any additives (contains 17/3 mg nitrate and 0.009 mg nitrite per 25 ml)Patients do not change the medication prescribed to them, during the intervention.

Category

Treatment - Other

2

Description

Control group: A12-week period with out any intervention Patients do not change the medication prescribed to them during the intervention

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Ghasemi Clinic, Sari, Iran

Full name of responsible person

Golbon Sohrab

Street address

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

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1981619573

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Email

golbonsohrab@sbmu.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Morteza Abdolahi
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No. 7, West Hafezi Ave., Farahzadi Blvd., Qods Town
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1981619573
Phone
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golbonsohrab@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Golbon Sohrab
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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No. 7, West Hafezi Ave., Farahzadi Blvd., Qods Town
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Person responsible for scientific inquiries

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Name of organization / entity
Shahid Beheshti University of Medical Sciences
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Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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Position
Assistant professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Only part of the data is shared, such as the original outcome.
When the data will become available and for how long
The start of the access period is 12 months after printing the results.
To whom data/document is available
It will be available for researchers working in academic and scientific institutions.
Under which criteria data/document could be used
It will be available for researchers working in academic and scientific institutions.
From where data/document is obtainable
golbonsohrab@sbmu.ac.ir
What processes are involved for a request to access data/document
The communication will be possible through the electronic mail given in the previous section.
Comments